JUN 2 2 2012

K112805

510(k) Summary for the Kimberly-Clark* Corporation
KIMGUARD ONE-STEP* Sterilization Wrap (Models KC100 – KC600)

Date of Submission:	September 9, 2011
Device type:	Sterilization Wrap
510(k) Submitter:	Brenda Shelkey Associate Director, Quality Assurance & Regulatory Affairs KIMBERLY-CLARK CORPORATION 1400 Holcomb Bridge Road Roswell, GA 30076 678-654-8021 Brenda.Shelkey@kcc.com Establishment Registration Number 1033422
Primary Contact for this 510(k) Submission:	Brenda Shelkey Associate Director, Quality Assurance & Regulatory Affairs KIMBERLY-CLARK CORPORATION 1400 Holcomb Bridge Road Roswell, GA 30076 678-654-8021 Brenda.Shelkey@kcc.com
Confidentiality Request:	Pursuant to 21 CFR 807.95, please treat with confidentiality the additional information presented in this notification and Kimberly-Clark's intent to market the medical devices described herein with changes.
Classification Regulation:	21 CFR 880.6850
Device Class:	Class II
Panel:	General Hospital
Product Code:	FRG

Intended Use:

KIMGUARD ONE-STEP* Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider by pre-vacuum steam at 270°F/132°C for 4 minutes or by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes. KIMGUARD ONE-STEP* Sterilization Wrap is also intended to be used in the Amsco® V-PRO™ 1 Low Temperature Sterilization System's cycle, the Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System's Lumen (identical to the V-PRO™ 1 Cycle) and Non Lumen Cycles, and the V-PRO™ Low Temperature Sterilization System's Flexible Cycle. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened within the period of time for which performance data demonstrating maintenance of sterility has been provided. The wrap was validated for aeration times for EO sterilization of 8 hours at 55 °C or 12 hours at 43.3 °C. The KIMGUARD ONE-STEP* Sterilization Wrap was validated for dry times for pre-vacuum steam sterilization of 20 minutes for Models 100 and 200, and for 30 minutes for Models 300, 400, 500, and 600. The KIMGUARD ONE-STEP* Sterilization Wrap was validated to be effectively aerated during the pre-programmed V-PRO™, the V-PRO™ 1 Plus, and the V-PRO™ Flexible Sterilization Cycles.

KIMGUARD ONE-STEP* Sterilization Wrap is not indicated for use for gravity steam sterilization.

Device Description: KIMGUARD ONE-STEP* Sterilization Wrap is comprised of two sheets of KIMGUARD* Sterilization Wrap ultrasonically seamed on two sides. This allows for convenient wrapping with two sheets simultaneously. The sheets of sterilization wrap are square or rectangular fabric produced using a polypropylene three-layer SMS (spunbond-meltblown-spunbond) process.

Substantial Equivalence: KIMGUARD ONE-STEP* Sterilization Wrap is substantially equivalent to the predicate Kimberly-Clark KIMGUARD* ONE-STEP* Sterilization Wrap (K082177,K091685, and K092167) in intended use, design, and materials.

Summary of Testing: KIMGUARD ONE-STEP* Sterilization Wrap was previously tested in compliance with the irritation and sensitization biocompatibility methods of ISO 10993 and cleared under K082177 and K091685. Sterilant penetration, dry time, and physical integrity were validated and cleared under K082177, K091685 and K092167. The wrap, Models KC300, KC400, KC500, and KC600, has been tested and shown to maintain sterility of pack contents after sterilization for at least one (1) year under standard conditions following pre-vacuum steam and ethylene oxide sterilization cycles. The wrap, Models KC100 and KC200, has been tested and shown to maintain

sterility of pack contents after sterilization for at least 30 days under standard conditions following pre-vacuum steam and ethylene oxide sterilization. The wrap, Models KC100, KC200, KC300, KC400, KC500, and KC600, has been tested and shown to maintain sterility of pack contents after sterilization for at least 30 days under standard conditions following sterilization with the Amsco V-PRO 1 and V-PRO 1 Plus and Flexible Cycle Low Temperature Sterilization Systems. Additionally, the wrap, Models KC100 through KC600, has been tested for use in the V-PRO™ Low Temperature Sterilization System's Flexible Cycle being considered under K102330 filed by STERIS Corporation.

Table 1. Wrap Model Recommendations for Pre-Vacuum Steam and Ethylene Oxide Sterilization Cycles[1]

KIMGUARD ONE-STEP* Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
KC100	Very Light Weight Package (for example: towel packs)	3 lbs	16 huck towels (17"x 29")
KC200	Light Weight Package (for example: standard linen packs)	6 lbs	2 huck towels (17"x 29") 2 fluid resistant U-drape (68"x109") 1 fluid resistant universal bar drape (70" x 108")
KC300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs	**For Pre-Vacuum Steam:** 15 huck towels (17"x 29") 1 small fluid resistant drape (60"x 76") 5 lbs of metal mass **For EO:** 16 huck towels 2 fluid resistant large drapes (76"x100") 1 fluid resistant small drape (76"x60") 1 fluid resistant table cover (60"x 90")
KC400[3]	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs	4 tray liners 20" x 25" stacked 10" x 10" x 3 ½ " tray containing 11 lbs of metal mass
KC500[3]	Heavyweight Package (for example: general use medical instruments)	17 lbs	4 tray liners 20" x 25" stacked 10" x 10" x 3 ½ " tray containing 15 lbs of metal mass
KC600[3]	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs	4 tray liners 20" x 25" stacked 10" x 10" x 3 ½ " tray containing 23 lbs of metal mass

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were

validated for the KIMGUARD ONE-STEP* Sterilization Wraps (i.e.: the number and size of the fluid resistant linens or the weight of the metal mass).

[3] The KC400, KC500, and KC600 model wraps were validated for sterilant penetration with 3 lbs of non-fluid resistant linen, and it is recommended to not exceed 3 lbs of non-fluid resistant linen in sterilization cycles with these models. It is recommended that the user not include fluid-resistant linens in KC400, KC500, and KC600 model wraps, as use of such fluid resistant materials has not been evaluated with these models.

Table 2. Wrap Model Recommendations for Amsco V-PRO™ 1, V-PRO 1 Plus and Flexible Cycle[1] Low Temperature Sterilization System

KIMGUARD ONE-STEP* Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
KC100	Very Light Weight Package (for example batteries)	3 lbs	• 3 lbs metal mass • 6 forceps
KC200	Light Weight Package (for example telescope with light cord)	6.5 lbs	• 2.5 lbs metal mass • 6 forceps • V-PRO tray (17" x 10" x 3½") at 4 lbs
KC300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs	• 5 lbs metal mass • 6 forceps • V-PRO tray (17" x 10" x 3½") at 4 lbs
KC400	Moderate to Heavy Weight Package (for example: general use medical instruments)	10 lbs	• 6 lbs metal mass • 6 forceps • V-PRO tray (17" x 10" x 3½") at 4 lbs
KC500	Heavyweight Package (for example: general use medical instruments)	10 lbs	• 5 lbs metal mass • 6 forceps • V-PRO tray (21" x 10" x 3½") at 5 lbs
KC600	Very Heavy Weight Package (for example: general use medical instruments)	10 lbs	• 5 lbs metal mass • 6 forceps • V-PRO tray (21" x 10" x 3½") at 5 lbs

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap grade is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the KIMGUARD ONE-STEP Sterilization Wraps (i.e.: the weight of the metal mass).

Table 3: Maintenance of Package Sterility Recommendations

Models	Pre-Vacuum Steam Sterilization	EO Sterilization	V-PRO Cycles
KIMGUARD One-Step* Sterilization Wrap Models KC100 and KC200	At least 30 days	At least 30 days	At least 30 days
KIMGUARD One-Step* Sterilization Wrap Models KC300, KC400, KC500 and KC600	At least 1 year	At least 1 year	At least 30 days

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Brenda Shelkey
Associate Director, Quality Assurance & Regulatory
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Building 300
Roswell, Georgia 30076

JUN 2 2 2012

Re: K112805
Trade/Device Name: KIMGUARD ONE- STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: June 14, 2012
Received: June 14, 2012

Dear Ms. Shelkey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K112805

Device Name: KIMGUARD ONE-STEP* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)

Indications for Use:

KIMGUARD ONE-STEP* Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider by pre-vacuum steam at 270°F/132°C for 4 minutes or by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes. KIMGUARD ONE-STEP* Sterilization Wrap is also intended to be used in the Amsco® V-PRO™ 1 Low Temperature Sterilization System's cycle, the Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System's Lumen (identical to the V-PRO™ 1 Cycle) and Non Lumen Cycles, and the V-PRO™ Low Temperature Sterilization System's Flexible Cycle. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened within the period of time for which performance data demonstrating maintenance of sterility has been provided. The wrap was validated for aeration times for EO sterilization of 8 hours at 55 °C or 12 hours at 43.3 °C. The KIMGUARD ONE-STEP* Sterilization Wrap were validated for dry times for pre-vacuum steam sterilization of 20 minutes for Models 100 and 200, and for 30 minutes for Models 300, 400, 500, and 600. The KIMGUARD ONE-STEP* Sterilization Wrap was validated to be effectively aerated during the pre-programmed V-PRO™, V-PRO™ 1 Plus, and the V-PRO™ Flexible Sterilization Cycles.

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth Francis-Wilcox

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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